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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	00952-8033	8881

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EXAMINER	
BERMAN, SUSAN W	

ART UNIT	PAPER NUMBER
1765	

NOTIFICATION DATE	DELIVERY MODE
06/21/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/764,445	MERRILL ET AL.	
	Examiner	Art Unit	
	SUSAN W. BERMAN	1765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *124-130 and 143-149* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *124-130,143-149* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-4-11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03-23-2011 has been entered.

Response to Arguments

Applicant's arguments filed 03-23-2011 have been fully considered but they are not persuasive with respect to the following issues.

Applicant's arguments are directed to establishing reduction to practice of the instant invention, as claimed, before the 7-9-96 filing date of Shen et al (6,228,900) and/or the 5-6-96 filing date of Hyon et al (6,168,626). These arguments are unpersuasive for reasons of record.

Applicant argues that the Examiner's comments on page 2 regarding Example 6 in Application SN 08/600744 and on page 3 regarding the photographs of a van de Graaff generator filed by applicant on 11-19-2009 appear contradictory. To clarify the examiner's comments, it is agreed that the photographs of the van de Graaff generator show a conveyor belt and that multiple doses would be employed to apply 20 Mrads total radiation at 2.5 Mrad/pass when using a conveyor belt method. A van de Graaff generator was used in Example 6 relied upon by applicant to establish the filing date of 08/600744. However, what is disclosed in Example 6 in SN 08/600744, filed 02-13-1996, is that the UHMWPE sample was heated in a chamber (melted) and that an electron beam was irradiated into the chamber through the thin foil at top such that a

maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. Irradiation was done using a van de Graaff generator with electrons of energy 2.5 MeV and a dose rate of 1.67 Mrad/min. The heating was stopped and the sample allowed to cool to room temperature in the chamber after irradiation. Example 6 does not mention a conveyor belt, cycles of radiation or heating the UHMWPE sample to melt after each passage on a conveyor belt through a van de Graaff generator to apply radiation. Example 6 describes irradiation by a beam entering the chamber through the thin foil at the top of the chamber. Example 6 further describes that the sample was removed from the chamber after the chamber and sample reached room temperature. Applicant's argument is not persuasive to establish an effective filing date of 02-13-1996 for the instant claims because it is not supported by the description of the process for irradiation with a van de Graaff generator in Example 6. Example 6 does not describe a conveyor method to irradiate the UHMWPE sample using a van de Graaff generator.

In any case, it is the examiner's position that the evidence presented does not establish that the use of a van de Graaff generator inherently requires using the conveyor method or inherently requires heating an UHMWPE sample that was not melted before the first irradiation pass to the melt after each passage through a van de Graaff generator on the conveyor belt. The evidence in the Declaration of Orhun K. Muratoglu filed 03-23-2011 taken with the disclosure in Example 6 of Application 08/600744 is not considered sufficient to show that a method of irradiating UHMWPE and subsequently melting the UHMWPE set forth in the instant claims and disclosed in Application 08/726313, having a filing date of 10-02-1996, was inherently disclosed in application 08/600744, having a filing date of 02-13-1996, that clearly discloses a method of melting and irradiating in the melt. The Declaration establishes that a conveyor belt

method can be used with a van de Graaff generator; however, the description of the method employed in Example 6 set forth in 08/600744 does not mention using a conveyor in the method of irradiation with a van de Graaff generator through thin foil at the top of a chamber containing the UHMWPE sample.

Applicant's arguments regarding inherency of process steps when using a van der Graaff generator are presented to establish an effective filing date of 02-13-1996. The relevant passage in the MPEP with respect to inherent functions or properties in a disclosure is as follows: "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". In the instant case, the mere fact that a van de Graaff generator may be used in a conveyor method is not sufficient to establish that it was used in such a method in Example 6 disclosed in SN 08/600744.

Applicant has filed, on 11-19-2009, photographs of a van der Graaff generator to further support applicant's argument of inherent features of the method of Example 6 wherein a van der Graaff generator is used to irradiate the UHMWPE sample. It is agreed that a conveyor belt is shown and that irradiation would be performed in multiple doses to reach 20 Mrads if the conveyor belt were employed. However, this is not persuasive with respect to the instant claim recitations, i.e., irradiating a fabricated article comprising UHMWPE, melting the irradiated UHMWPE, allowing the crosslinked UHMWPE to cool, and forming an implant for the crosslinked UHMWPE. These method steps are clearly disclosed in the Examples, such as

Example 8, in the instant specification and in SN 08/726313 representing irradiation and subsequent melting.

The instantly recited steps are: irradiating a fabricated article comprising UHMWPE, melting the irradiated UHMWPE, allowing the crosslinked UHMWPE to cool, and forming an implant for the crosslinked UHMWPE. These process steps are not disclosed in Example 6. Specifically, the sample in Example 6 is melted and then irradiated, following which heating is stopped after irradiation and the sample is cooled to room temperature. The instantly recited method steps were first disclosed in SN 08/726,313, filed 10-02-1996. See Example 8 in the instant specification, which first appeared in SN 08/726,313.

With regard to applicant's remarks concerning MPEP §2163.07(a), the cited MPEP section states that an application may be amended to recite a function, theory or advantage of a device that inherently performs a function, operates according to a theory or has an advantage without introducing new matter. Thus applicant may amend the specification to include a known function of the van de Graaff generator. However, this section of the MPEP does not suggest amending the specification to introduce a method employing the known function that is materially different from the method that was originally disclosed. There is no suggestion in Example 6 that the van de Graaff generator was used with a conveyor belt or that the sample was other than stationary in the disclosed chamber or that the sample was not melted before being irradiated and was then melted after having been irradiated.

Applicant's arguments that the evidence presented in the Rule 1.131 Declaration of Merrill et al filed 11-19-2009 shows reduction to practice before January 20, 1995 is unpersuasive for reasons of record. Evidence that polyethylene is first melted and then irradiated

is not evidence of reduction to practice of a method wherein UHMWPE is irradiated and then melted.

Applicant's argument that claims 128-129 are supported by the disclosure of SN 08/600744 is unpersuasive. Example 4 discloses swell ratio for melt-irradiated UHMWPE (GUR 415) that was melted and then irradiated while molten (Example 2). Degree of oxidation is not mentioned. Example 11, Tables 8 and 11 are not disclosed in 08/600744. The instant claims recite that the method is to irradiate a fabricated article of UHMWPE and then heat the irradiated fabricated article, i.e. the UHMWPE is not melted before it is irradiated.

Claim Interpretation and Effective Filing Date

Claims 124-127, 130 and 143-149, recite a process wherein irradiation of UHMWPE is subsequently followed by heating or melting: a method ("IR-SM") first disclosed in SN 08/726,313, filed 10-02-1996. Claims 124-127, 130 and 143-149, require that the irradiation step precede the heating or melting step, therefor, the effective filing date of the claims is 10/02/1996. The instant claims are considered to be fully supported by the disclosure of SN 08/726,313, but not by the disclosure of SN 08/600744, filed 02-13-1996, wherein a method of irradiating UHMWPE in the molten state is disclosed but subsequent melting after irradiation is not mentioned. Therefore, the earliest effective filing date of instant claims 124-127, 130 and 143-149 is considered to be the 10/02/1996 filing date of SN 08/726,313.

Claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN '744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN '744. SN '313 does disclose

the swell ratio or degree of oxidation of the disclosed UHMWPE, therefor, the effective filing date for claims 128-129 is considered to be 10/02/1996.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and 128 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 127 and 136 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN W. BERMAN whose telephone number is (571)272-1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
6/14/2011

/SUSAN W BERMAN/
Primary Examiner, Art Unit 1765